AUG 1 0 2001

K012170
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SOREDEX

510(k) Summary

Date
July 10, 2001

Submitters Information
Soredex Instrumentarium Corporation
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Finland
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Contact: Kai Lanér

Trade Name
Digora PCT

Common Name
Imaging plate reader

Classification
Solid state x-ray imager

Predicate Device
On physical performance:
Digora
510(k): K934949
On diagnostic performance:
Conventional film screen combination

Product Description
A digital radiography system for imaging plates located in cassettes. The system may be used with x-ray equipment utilizing film or similar cassettes. The image is recorded on reusable imaging plate which substitutes for conventional x-ray film. The x-ray energy absorbed in the imaging plate remains stored as a latent image. When fed to the device the stored energy is released as an optical emission proportional to the stored energy when the imaging plate is stimulated pixel by pixel by a scanning laser. An optical system collects the emission for photoelectronic system, which converts the emission to digital electronic signals. These signals are processed in a computer system which formats and stores the signals.

Further image processing, display and achieving are carried out with an auxiliary software (such as Digora for Windows K983267), a PC and a CRT.

Intended Use
The Digora PCT imaging system is indicated for capturing, digitization and processing of extraoral, maxillofacial and cephalometric x-ray images stored in imaging plate recording media.

Technological Characteristics
The subject device represents a change to the predicate device in form of reading larger imaging plates such as 15 cm x 30 cm, 18 cm x 24 cm and 24 cm x 30 cm or 8 inch x 10 inch and 10 inch x 12 inch. The image pixel bit depth in the predicate device is 8 bits and correspondingly in the subject device 16 bits.

Performance data
A comparison between Digora PCT and Digora was made to evaluate the need of dose to produce equal pixel value of a known object and the spatial resolution. The dose required to for a certain pixel-value was a ¼ of that required for Digora. Spatial resolution for Digora PCT is 4 lp/mm, and 6 lp/mm for Digora. Digora PCT was found to be substantially equivalent to Digora.
A comparison between Digora PCT and Kodak T-Mat G film/Lanex Regular intensifying screens was made to evaluate the ability of the device to provide images of equivalent diagnostic capability to those of a cleared predicate device. Digora PCT was found to be substantially equivalent to a film screen combination.

Conclusion
Digora PCT has found to have substantially equivalent physical performance as the predicate device Digora.
Digora PCT is shown to be able to provide images of equivalent diagnostic capability to those of a cleared film screen combination.
Digora PCT is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

Mr. Kai Laner
Director
Soredex Instrumentarium Corporation
Nilsiankatu 10 - 14
FIN 00510 Helsinki
Finland

Re: K012170
Digora PCT (Imaging plate reader)
Dated: July 10, 2001
Received: July 12, 2001
Regulatory Class: II
21 CFR 892.1630/Procode: 90 MQB

Dear Mr. Laner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (special Controls) or class III (premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as Set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 592-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 592-4639. Also, please note the regulation entitled, "Misbranding by reference notification" (21CFR 807.97). Othr general information on your responsibilities under the Act may be obtained from the Division of Small Manufactures International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address http://www.da.gov/cdrh/dsma/dsmamain.html.

Sincerely Yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

510 (k) NUMBER : K012170

DEVICE NAME : DIGORA PCT

INDICATIONS FOR USE :

The Digora PCT imaging system is indicated for capturing, digitization and processing of extraoral, maxillofacial and cephalometric x-ray images stored in imaging plate recording media.

Prescription Use ✓

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012170